SERONO S A
Form 6-K
July 24, 2006

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of **July**

Commission File Number **1-15096**

Serono S.A.

(Translation of registrant s name into English)

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(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F. Form 20-F x Form 40-F o

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes o No x

If Yes is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82- .

Media Release

FOR IMMEDIATE RELEASE

SERONO INITIATES FIRST LARGE SCALE EUROPEAN PHARMACO-EPIDEMIOLOGICAL STUDY IN PSORIASIS TO FURTHER DOCUMENT THE DEMONSTRATED LONG-TERM SAFETY PROFILE OF RAPTIVA®

CLEAREST™: Prospective Seven-Year Cohort Study in 7,000 Patients Treated With Raptiva® Will Gather Largest Natural History of Psoriasis

Geneva, Switzerland July 24, 2006 Serono (virt-x: SEO and NYSE: SRA) announced today that it has initiated CLEAREST™ (**CL**inical **E**xperience **A**cquired with **R**aptiva® in **E**urope with a **S**even year **T**rial), the first large-scale pharmaco-epidemiological study in psoriasis in Europe. The primary objective of this prospective, seven-year cohort study is to gather additional long-term safety data of Raptiva® in clinical practice to further support its already established favorable benefit-risk ratio. The study shall include 7,000 adult patients with moderate-to-severe plaque psoriasis.

The initiation of CLEAREST™ shows Serono s strong commitment to psoriasis patients, said Franck Latrille, Senior Executive Vice President Global Product Development of Serono. The study will not only provide physicians with additional clinical evidence of the long-term safety profile of Raptiva® in psoriasis in clinical practice, but also help to gather scientific data on the long-term safety profile of other agents used to treat psoriasis. With data of approximately 18,000 patient years, the study will create the largest database of natural history of psoriasis, its treatments in clinical practice and thus add considerable scientific knowledge about the disease.

CLEAREST™ is a multinational, multicenter study and will be conducted in dermatology centers of European hospitals, as well as in private dermatology practices. Patients starting the study will receive Raptiva®; those discontinuing Raptiva® during the study will remain included in the study cohort, regardless of their new treatment. The study will therefore allow for multiple long-term cohort comparisons, including a comparison of the cohort of patients exposed to Raptiva® versus the non-exposed patients, as well as the Raptiva®-treated cohort versus the General Practice Research Database (GPRD)1. Yearly interim analyses of the seven-year study will be presented at major dermatology meetings.

CLEAREST™ will further expand today s well-established clinical evidence on the efficacy and safety of Raptiva® by gathering long-term safety data on approximately 18, 000 patient years in clinical practice. To date, the long-term safety and efficacy of treatment with Raptiva® has been demonstrated in clinical study populations with moderate-to-severe psoriasis, including the CLEAR study, as well as a three-year, phase IIIb open-label study performed in North America. Globally, more than 30,000 patients have received Raptiva®, both during clinical trials and post registration.

1 The GPRD is a large UK database which encompasses around three million people who are enrolled with selected general practitioners covering more than 30 million patient-years of follow-up. This database will provide strong comparative epidemiologic data.

This represents more than 17,500 patient years of exposure, creating one of the largest existing databases of patients taking a biological therapy for psoriasis.

About CLEAREST™

CLEAREST™ (**CL**inical **E**xperience **A**cquired with **R**aptiva® in **E**urope with a **S**even year **T**rial) is a prospective, seven-year cohort study, which is designed to further document the demonstrated long-term safety profile of Raptiva® in over 7,000 adult patients with moderate-to-severe plaque psoriasis. The primary objective of the study is to document the incidence of adverse events in patients treated with Raptiva®. The secondary objective, in addition to documenting the incidence of adverse events, is to compare the incidence rates of the primary endpoints observed in patients treated with Raptiva® with those incidence rates observed in the most adequate comparison cohort, i.e. a cohort of patients who have discontinued Raptiva® (internal comparison) and external comparison with psoriasis patients of the GPRD (General Practice Research Database) cohort. Patients are eligible to be included into the study, if they are starting or already receiving Raptiva® based on the investigator s assessment and in accordance with the indication of the European SmPC. It is planned that patients discontinuing Raptiva® will remain included in the study cohort, regardless of their new treatment. CLEAREST™ is a multinational, multicenter study, initiated in 2006 in various dermatology centers of European hospitals, as well as in private dermatology practices. Yearly interim analyses will include incidence analysis and will be presented at major dermatology congresses.

In the United States, Genentech Inc. initiated in 2005 the observational study RESPONSE, with the objective to further evaluate the long-term safety data on patients receiving Raptiva® in clinical practice and to compare the results with long-term data from patients receiving therapy with other biological agents. The study period is planned for up to five years and will include approximately 5,000 patients treated with Raptiva®, as well as 2,500 comparison patients treated with other biological therapy.

About Raptiva®

Raptiva® (efalizumab) is a humanized therapeutic antibody designed to selectively and reversibly block the activation, reactivation and trafficking of T-cells that lead to the development of psoriasis symptoms. Raptiva® is designed to be administered once weekly via subcutaneous injection and can be self-administered by patients at home.

Raptiva® received EU approval for the *Treatment of adult patients with moderate to severe chronic plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate and PUVA* .

Adverse events observed with Raptiva® include headache, non-specific infection (e.g., common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. There is no evidence of accumulation or cumulative toxicity to date.

Serono has the rights to develop and market Raptiva® worldwide outside of the United States and Japan. To date, Raptiva® is available in over 50 countries, amongst them many countries in Europe, Latin America, Asia as well as Australia. Development and marketing rights in the United States, where Raptiva® has been available since November 2003, remain with Genentech Inc.

About Psoriasis

Psoriasis is a T-cell mediated disease, which occurs when skin cells grow abnormally, resulting in thick, red, scaly, inflamed patches. Plaque psoriasis, the most common form of the disease is characterized by inflamed patches of skin (lesions) topped with silvery white scales. Psoriasis can be limited to a few spots or involve extensive areas of the body, appearing most commonly on the knees, elbows, trunk, and scalp. Although it is highly visible, psoriasis is not a contagious disease. While there are a number of medications that may help control the symptoms of psoriasis, there currently is no known permanent cure.

Background material

For free B-roll, video and other content for Serono and its products, please visit the Serono Media Center www.thenewsmarket.com/Serono. You can download print-quality images and receive broadcast-standard video digitally or by tape from this site. Registration and video is free to the media.

About Serono

Serono is a global biotechnology leader. The Company has eight biotechnology products, Rebif®, Gonal-f®, Luveris®, Ovidrel®/Ovitrelle®, Serostim®, Saizen®, Zorbtive and Raptiva®. In addition to being the world leader in reproductive health, Serono has strong market positions in neurology, metabolism and growth and has recently entered the psoriasis area. The Company s research programs are focused on growing these businesses and on establishing new therapeutic areas, including oncology and autoimmune diseases.

In 2005, Serono, whose products are sold in over 90 countries, achieved worldwide revenues of US$2,586.4 million. Reported net loss in 2005 was US$106.1 million, reflecting a charge of US$725 million taken relating to the settlement of the US Attorney s Office investigation of Serostim. Excluding this charge as well as other non-recurring items, adjusted net income grew 28.4% to US$565.3 million in 2005. Bearer shares of Serono S.A., the holding company, are traded on the virt-x (SEO) and its American Depositary Shares are traded on the New York Stock Exchange (SRA).

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Some of the statements in this press release are forward looking. Such statements are inherently subject to known and unknown risks, uncertainties and other factors that may cause actual results, performance or achievements of Serono S.A. and affiliates to be materially different from those expected or anticipated in the forward-looking statements. Forward-looking statements are based on Serono s current expectations and assumptions, which may be affected by a number of factors, including those discussed in this press release and more fully described in Serono s Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission on February 28, 2006. These factors include any failure or delay in Serono s ability to develop new products, any failure to receive anticipated regulatory approvals, any problems in commercializing current products as a result of competition or other factors, our ability to obtain reimbursement coverage for our products, the outcome of government investigations and litigation and government regulations limiting our ability to sell our products. Serono has no responsibility to update the forward-looking statements contained in this press release to reflect events or circumstances occurring after the date of this press release.

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SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SERONO S.A.,
a Swiss corporation
(Registrant)

Date July 24, 2006

By: /s/ Stuart Grant
Name: Stuart Grant
Title: Chief Financial Officer